

## CRITERIA FOR PRIOR AUTHORIZATION

## Antidepressant Medications – Safe Use for All Ages

**BILLING CODE TYPE** For drug coverage and provider type information, see the [KMAP Reference Codes webpage](#).

**MANUAL GUIDELINES** Prior authorization will be required for all current and future dose forms available of the medications below:

<b>Amitriptyline</b> (Elavil®)	<b>Levomilnacipran</b> (Fetzima®)
<b>Amoxapine</b>	<b>Maprotiline</b>
<b>Bupropion</b> (Forfivo® XL, Wellbutrin®, Wellbutrin® SR, Wellbutrin® XL)	<b>Milnacipran</b> (Savella®)
<b>Citalopram</b> (Celexa®)	<b>Nefazodone</b>
<b>Clomipramine</b> (Anafranil®)	<b>Nortriptyline</b> (Pamelor®)
<b>Desipramine</b> (Norpramin®)	<b>Olanzapine/Fluoxetine</b> (Symbyax®)
<b>Desvenlafaxine</b> (Khedezla®, Pristiq®)	<b>Paroxetine</b> (Paxil®, Paxil CR®, Pexeva®)
<b>Doxepin</b> (Sinequan®)	<b>Phenelzine</b> (Nardil®)
<b>Duloxetine</b> (Cymbalta®, Drizalma Sprinkle™)	<b>Protriptyline</b> (Vivactil®)
<b>Escitalopram</b> (Lexapro®)	<b>Selegiline</b> (Emsam®)
<b>Esketamine</b> (Spravato®)	<b>Sertraline</b> (Zoloft®)
<b>Fluoxetine</b> (Prozac®, Prozac Weekly®)	<b>Tranylcypromine</b> (Parnate®)
<b>Fluvoxamine</b> (Luvox®, Luvox CR®)	<b>Trimipramine</b> (Surmontil®)
<b>Imipramine</b> (Tofranil®, Tofranil® PM)	<b>Venlafaxine</b> (Effexor®, Effexor XR®)
<b>Isocarboxazid</b> (Marplan®)	<b>Vilazodone</b> (Viibryd®)
	<b>Vortioxetine</b> (Trintellix®)

## CRITERIA FOR PRIOR AUTHORIZATION FOR ANTIDEPRESSANTS MEDICATIONS:

- For all agents listed, the preferred PDL drug, if applicable, which covers this indication, is required unless the patient meets the non-preferred PDL PA criteria.
- MULTIPLE CONCURRENT USE:
  - Each of the following criteria for multiple concurrent use will require prior authorization:
    - For patients **< 13 years of age**, two or more different antidepressants used concurrently for greater than 60 days
    - For patients **≥ 13 years of age**, three or more different antidepressants used concurrently for greater than 60 days
    - Two or more different selective serotonin reuptake inhibitors (SSRIs) used concurrently for greater than 60 days (defined in table 1)
    - Two or more different serotonin norepinephrine reuptake inhibitors (SNRIs) used concurrently for greater than 60 days (defined in table 2)
    - Two or more different tricyclic antidepressants (TCAs) used concurrently for greater than 60 days (defined in table 3)

## DRAFT PA Criteria

- Prior authorization will require written peer-to-peer consult with health plan psychiatrist, medical director, or pharmacy director for approval, followed by a verbal peer-to-peer if unable to approve written request.

**LENGTH OF APPROVAL:** 12 months

**RENEWAL CRITERIA:** Patient is stable and has been seen in the past year.

## CRITERIA FOR PRIOR AUTHORIZATION FOR ESKETAMINE (SPRAVATO™) NASAL SPRAY:

- Age ≥ 18 years of age.<sup>7</sup>
- Patient must have a diagnosis of treatment-resistant depression, including ALL of the following:
  - DSM-5 criteria for major depressive disorder.
  - Inadequate response (in the current episode) to at least 3 different antidepressants (listed in Tables 1-4) despite therapeutic dose and 6 weeks<sup>1</sup> duration of each medication.
- Patient must be maintained on antidepressant(s) while on therapy with Spravato.
- Patient must have an adequate trial (at least 4 weeks) of at least ONE of the following augmentation therapies, or a contraindication to all therapies listed in Table 5:<sup>1</sup>
  - Addition of a second-generation antipsychotic listed in Table 5 to the current regimen.
  - Addition or change in medication therapy to a fixed-dose combination product of olanzapine/fluoxetine.
- Prescriber must provide baseline Montgomery-Asberg Depression Rating Scale (MADRS) or Hamilton Depression scale (HAM-D) or Patient Health Questionnaire (PHQ-9) before initial treatment with intranasal esketamine.
  - Patient must have severe depression as defined by MADRS or HAM-D or the PHQ-9. See Table 6 below.
- Patient, provider, and provider's staff must be registered, educated, and be in good standing with the associated REMS program.
- Dose does not exceed 168mg (6 nasal spray devices) per week for induction (initial 4 weeks).<sup>7</sup>
- Dose does not exceed 84mg (3 nasal spray devices) per week for maintenance (beyond initial 4 weeks).<sup>7</sup>
- Patient must be screened for active/risk for substance use disorder.
- Prescriber has addressed the appropriateness of psychotherapy with the patient.

**LENGTH OF INITIAL APPROVAL:** 6 months

## RENEWAL CRITERIA:

- Prescriber must provide the following response measure(s).
  - Stable response was maintained, defined as MADRS or HAM-D or PHQ-9 average decrease ≥50% from baseline, with a minimum of 3 assessments with the same tool.
- Patient has < 2 relapses since the most recent approval. A relapse is defined as hospitalization or overnight observation for worsening depression.
- Patient must be screened for active/risk for substance use disorder.
- Dose does not exceed 84mg (3 nasal spray devices) per week for maintenance.<sup>7</sup>

**LENGTH OF APPROVAL FOR RENEWAL:** 12 months

## DRAFT PA Criteria

**TABLE 1. SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIs)**

SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIs)
Citalopram (Celexa®)
Escitalopram (Lexapro®)
Fluoxetine (Prozac®, Prozac Weekly®)
Fluvoxamine (Luvox®, Luvox CR®)
Paroxetine (Paxil®, Paxil CR®, Pexeva®)
Sertraline (Zoloft®)
Vilazodone (Viibryd®)*
Vortioxetine (Trintellix®)**

\*Vilazodone also has partial agonistic 5-HT<sub>1A</sub> activity

\*\*Vortioxetine also has agonistic 5-HT<sub>1A</sub> and antagonistic 5-HT<sub>3</sub> activity

**TABLE 2. SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS (SNRIs)**

SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS (SNRIs)
Desvenlafaxine (Khedezla®, Pristiq®)
Duloxetine (Cymbalta®, Drizalma Sprinkle™)
Levomilnacipran (Fetzima®)
Milnacipran (Savella®)
Venlafaxine (Effexor®, Effexor XR®)

**TABLE 3. TRICYCLIC ANTIDEPRESSANTS (TCAs)**

TRICYCLIC ANTIDEPRESSANTS (TCAs)
Amitriptyline (Elavil®)
Amoxapine
Clomipramine (Anafranil®)
Desipramine (Norpramin®)
Doxepin (Sinequan®)
Imipramine (Tofranil®)
Imipramine Pamoate (Tofranil® PM)
Nortriptyline (Pamelor®)
Protriptyline (Vivactil®)
Trimipramine (Surmontil®)
TETRACYCLIC ANTIDEPRESSANTS
Maprotiline

**TABLE 4. OTHER ANTIDEPRESSANTS**

DOPAMINE NOREPINEPHRINE REUPTAKE INHIBITORS
Bupropion (Forfivo® XL, Wellbutrin®, Wellbutrin® SR, Wellbutrin® XL)
SEROTONIN MODULATORS
Nefazodone (Serzone)
Monoamine Oxidase Inhibitors (MAOIs)
Phenelzine (Nardil®)
Tranylcypromine (Parnate®)
Isocarboxazid (Marplan)
Selegiline transdermal system (Emsam®)

# DRAFT PA Criteria

TABLE 5. AUGMENTATION THERAPIES<sup>1,8-11</sup>

SECOND-GENERATION ANTI-PSYCHOTICS (SGAs)
Aripiprazole (Abilify®)
Brexipiprazole (Rexulti®)
Olanzapine/fluoxetine (Symbyax®) (fixed combination product)
Quetiapine Extended Release (Seroquel XR®)

TABLE 6. CUTOFFS FOR SEVERE DEPRESSION<sup>3-4</sup>

RATING SCALE	CUTOFF SCORE FOR SEVERE DEPRESSION
MADRS	≥ 35
HAM-D	≥ 19
PHQ-9	≥ 20

TABLE 7. ANTIDEPRESSANT MEDICATION DOSING LIMITS

MEDICATION	PEDIATRIC MINIMUM AGE (YEARS) (LITERATURE-BASED)**	PEDIATRIC MAX DOSE/DAY (LITERATURE-BASED)**	ADULT MAX DOSE/DAY (FDA-APPROVED)
<a href="#">Amitriptyline (Elavil®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">300mg</a>
<a href="#">Amoxapine</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">400mg</a>
<a href="#">Bupropion (Forfivo® XL)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">450mg</a>
<a href="#">Bupropion (Wellbutrin®)</a>	<a href="#">≥6</a>	<a href="#">≤6mg/kg or 300mg</a>	<a href="#">450mg</a>
<a href="#">Bupropion (Wellbutrin® SR)</a>		<a href="#">400mg</a>	<a href="#">400mg</a>
<a href="#">Bupropion (Wellbutrin® XL)</a>		<a href="#">450mg</a>	<a href="#">450mg</a>
<a href="#">Citalopram (Celexa®)</a>	<a href="#">≥6</a>	<a href="#">40mg</a>	<a href="#">40mg</a>
<a href="#">Clomipramine (Anafranil®)</a>	<a href="#">≥10</a>	<a href="#">≤3mg/kg or 200mg</a>	<a href="#">200mg (OCD)</a>
<a href="#">Desipramine (Norpramin®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">150mg</a>
<a href="#">Desvenlafaxine (Khedezla®, Pristiq®)</a>	<a href="#">≥7</a>	<a href="#">50mg</a>	<a href="#">100mg</a>
<a href="#">Doxepin (Sinequan®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">300mg</a>
<a href="#">Duloxetine (Cymbalta®, Drizalma Sprinkle™)</a>	<a href="#">≥7</a>	<a href="#">120mg</a>	<a href="#">120mg</a>
<a href="#">Escitalopram (Lexapro®)</a>	<a href="#">≥6</a>	<a href="#">20mg</a>	<a href="#">20mg</a>
	<a href="#">≥12</a>	<a href="#">30mg</a>	<a href="#">20mg</a>
<a href="#">Esketamine (Spravato®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">Induction (initial 4 weeks): 168mg/week, Maintenance: 84mg/week</a>
<a href="#">Fluoxetine (Prozac®, Prozac Weekly®)</a>	<a href="#">≥6</a>	<a href="#">60mg</a>	<a href="#">80mg</a>
<a href="#">Fluvoxamine (Luvox®)</a>	<a href="#">≥8</a>	<a href="#">200mg</a>	<a href="#">200mg (OCD)</a>
	<a href="#">≥12</a>	<a href="#">300mg</a>	<a href="#">300mg (OCD)</a>
<a href="#">Fluvoxamine (Luvox CR®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">300mg (OCD)</a>
<a href="#">Imipramine HCl (Tofranil®)</a>	<a href="#">≥6</a>	<a href="#">2.5mg/kg/day</a>	<a href="#">200mg</a>
<a href="#">Imipramine pamoate (Tofranil PM®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">300mg</a>
<a href="#">Isocarboxazid (Marplan)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">60mg</a>
<a href="#">Levomilnacipran (Fetzima®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">120mg</a>
<a href="#">Maprotiline</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">150mg</a>

## DRAFT PA Criteria

<a href="#">Milnacipran (Savella®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">200mg (fibromyalgia)</a>
<a href="#">Nefazodone</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">200mg</a>
<a href="#">Nortriptyline (Pamelor®)</a>	<a href="#">≥6</a>	<a href="#">≤2mg/kg or 100mg</a>	<a href="#">150mg</a>
<a href="#">Paroxetine (Paxil®, Pexeva®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">50mg</a>
<a href="#">Paroxetine (Paxil CR®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">62.5mg</a>
<a href="#">Phenelzine (Nardil®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">90mg</a>
<a href="#">Protriptyline (Vivactil®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">60mg</a>
<a href="#">Selegiline transdermal system (Emsam®)</a>	<a href="#">≥12</a>	<a href="#">12mg per 24 hours</a>	<a href="#">12mg</a>
<a href="#">Sertraline (Zoloft®)</a>	<a href="#">≥6</a>	<a href="#">200mg</a>	<a href="#">200mg</a>
<a href="#">Tranylcypromine (Parnate®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">60mg</a>
<a href="#">Trimipramine (Surmontil®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">200mg</a>
<a href="#">Venlafaxine (Effexor®, Effexor XR®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">225mg (IR), 375mg (ER)</a>
<a href="#">Vilazodone (Viibryd®)</a>	<a href="#">≥12</a>	<a href="#">30mg</a>	<a href="#">40mg</a>
<a href="#">Vortioxetine (Trintellix®)</a>	<a href="#">Not Approved</a>	<a href="#">Not Approved</a>	<a href="#">20mg</a>

\*Not Approved means insufficient evidence available or pediatric dosing was reviewed, but not recommended.

\*\*Adapted from the Texas Department of Family and protective Services. See reference #2 below.

### Notes:

- Mirtazapine, and trazodone are FDA-indicated for depression, but are not listed because they are primarily used for other indications.

### References:

1. Practice Guideline for the Treatment of Patients with Major Depressive Disorder, Third Edition. American Psychiatric Association, October 2010. Available at <https://psychiatryonline.org/guidelines>. Accessed 7/24/19.
2. Psychotropic Medication Utilization Parameters for Children and Youth In Texas Public Behavioral Health (6<sup>th</sup> Version). The Parameters Workgroup of the Psychiatric Executive Formulary Committee, Health and Specialty Care Division, Texas Health and Human Services Commission, June 2019. Available at [https://www.dfps.state.tx.us/Child\\_Protection/Medical\\_Services/Psychotropic\\_Medications.asp](https://www.dfps.state.tx.us/Child_Protection/Medical_Services/Psychotropic_Medications.asp). Accessed 10/23/19.
3. Grade Scores of the Montgomery-Asberg Depression and the Clinical Anxiety Scales. Br J Psychiatry 1986; 148:599-601. Available at <https://www.cambridge.org/core/journals/the-british-journal-of-psychiatry/article/grade-scores-of-the-montgomeryasberg-depression-and-the-clinical-anxiety-scales/E03CC2A39EEE29F47DAAE56A48B4EA60>. Accessed 9/17/19.
4. Severity classification on the Hamilton depression rating scale. J Affect Disord 2013; 150(2):384-8. Available at <https://www.sciencedirect.com/science/article/abs/pii/S0165032713003017?via%3Dihub>. Accessed on 9/17/19.
5. Patient Health Questionnaire (PHQ9). Available at <https://www.integration.samhsa.gov/clinical-practice/screening-tools>. Accessed 10/21/19.
6. Zimmerman, M. Using the 9-item Patient Health Questionnaire to Screen for and Monitor Depression. JAMA October 2019. [Epub ahead of print]. Available at <https://jamanetwork.com/journals/jama/article-abstract/2753532>. Accessed on 10/22/19.
7. Spravato (esketamine) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; May 2019.
8. Abilify (aripiprazole) [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; February 2017.
9. Rexulti (brexipiprazole) [package insert]. Otsuka America Pharmaceutical, Inc.; February 2018.
10. Symbyax (olanzapine/fluoxetine) [package insert]. Indianapolis, IN: Lilly USA, LLC; March 2018.
11. Seroquel XR (quetiapine) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2018.

---

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

---

PHARMACY PROGRAM MANAGER  
DIVISION OF HEALTH CARE FINANCE  
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

---

DATE

---

DATE